COVIFIND™

ENG

By Meril

INSTRUCTION FOR USE

COVID-19 ANTIGEN SELF TEST

CE 1434

Scan the QR code for more information on COVIFIND.
Website: www.covifind.au
Contact Helpline number: +61 298461908
Working hours: This service is available between 9 am and 7 pm (AEST), or 9 am and 8 pm (AEDT), 7 days per week.

SUMMARY:
Corona viruses belong to the Nidovirales Coronaviridae and Corona virus a large class of viruses found widely in nature. People are generally susceptible. Currently the patients infected by the novel Corona Virus are the main source of infection. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestation includes fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

INTENDED USE:
COVIFIND COVID-19 Antigen Self Test is an In-Vitro diagnostics immunochromatographic rapid assay kit for the qualitative detection of SARS-CoV-2 specific antigen in nasal swab specimens from symptomatic individuals. This test is intended for collection of nasal specimens from individuals aged 18 years or older who have experienced COVID like symptoms within the last seven days and for use in the home, workplace or elsewhere as an aid to diagnosis of SARS-CoV-2 infection. Anyone under 18 years will require adult supervision or assistance.

PRINCIPLE:
COVIFIND COVID-19 Antigen Self Test is an immunoassay kit for rapid and qualitative determination of SARS-CoV-2 infection from swab specimens. Monoclonal anti-SARSCoV- 2 nucleocapsid antibody is coated on the test line region. Antigens of SARS-CoV-2 in the specimens react with the anti-SARS-CoV-2 monoclonal nucleocapsid antibody coupled with old conjugate, and form an antigen-antibody complex followed by reaction with anti-SARS-CoV-2 monoclonal nucleocapsid antibodies immobilized in the test line. This complex migrates on the membrane, where it will be captured by the monoclonal anti- SARS-CoV-2 antibody. A colored test line would be visible in the result window if SARSCoV- 2 antigens are present in the specimen. The intensity of colored test line will vary depending upon the amount of SARS-CoV-2 antigen present in the specimen. If SARSCoV- 2 antigens are not present in the specimen, then no line appears in the test line. The control band is used for procedural control and should always appear if the test procedure is performed correctly.

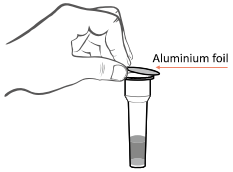
Test Preparation:

Wash your hands.
Make sure they are dry before starting the test.

Remove the test components from the box and place them on a flat surface.

Remove the test device from the pouch.

Peel the Aluminium foil from the pre-filled buffer tube.



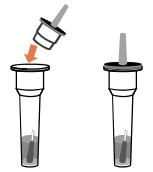
Sample Collection: Step 2

Carefully insert the swab into one nostril 2-4 cm or until resistance is met.

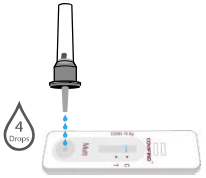
Slowly rotate the Swab, gently rubbing it along the insides of your nasal passage at least 5 times.

Using the same swab, repeat in the other nostril.

Secure the cap on top of the buffer tube.



Test Procedure:



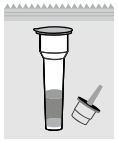
Squeeze 4 drops of fluid from the tube into the sample well of the test device.

Read results at 15 minutes. Do not read results after 20 minutes.

(*Do not leave the test device unused once opened for a longer duration Use the test device immediately.)

Kit Contents:

1 x Pre-filled buffer Tube with cap



1 x Sterile Nasal Swab

1 x Test Device

Disposal Bag

1x Disposal Bag

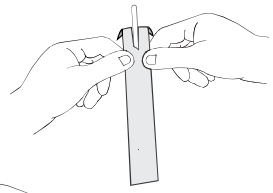
1x IFU

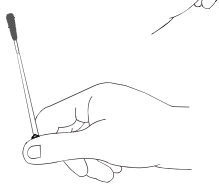
Kit Content	CFCAST-01 1 (Test)	CFCAST-02 5 (Test)	CFCAST-03 10 (Tests)	CFCAST-04 25 (Tests)	CFCAST-05 50 (Tests)
Quantity per kit					
Pre-filled Buffer tube with cap	01	05	10	25	50
Sterile Nasal Swab	01	05	10	25	50
Test Device	01	05	10	25	50
Disposal Bag	01	05	10	25	50
IFU	01	01	02	25	50

Push the buffer tube on to the perforated circle.

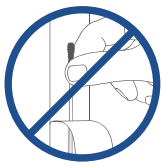
Sample Collection: Step 1

Remove the sterile swab from the tail end.



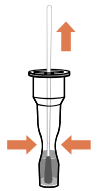


DO NOT TOUCH THE SWAB HEAD



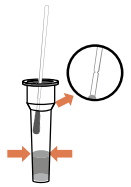
Sample Collection: Step 3

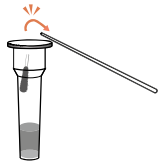
Insert the swab in the buffer tube and swirl it 8-10 times in the fluid.



Pinch the Swab tip through the Tube to remove any remaining fluid.

Hold the buffer tube firmly, lift the swab till breakpoint and snap the swab handle at breakpoint.



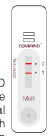


Leave the swab inside the tube and discard the stick.

Result Interpretation:

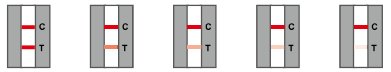
The faint blue line at "Control" position is always visible before testing. This faint blue line should not be interpreted as Control line during result interpretation. A reddish purple band is expected at the control band if the test has been conducted properly.

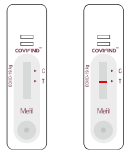
Positive Result
If both the Control line "C" and the Test line "T" appear, the result is Positive.
Note - If you test COVID positive then follow the guidance from your local state or territory health department for guidance on confirmation testing if necessary and if unwell seek medical assistance. You should also inform the immediate contacts that you have had in past 24 hours so they can take any appropriate precautions.



Negative Result
If there is only control line "C"and no test line "T" visible, the result is Negative.
Note - Negative results may require additional testing to confirm your results if you are symptomatic. If symptomatic, continue antigen testing every 24 hours for 3 days or follow the guidance from your local state or territory health department for guidance on confirmation testing if necessary and if unwell seek medical assistance. If asymptomatic, it is likely that you were not infectious at the time the test was taken. A negative test result, however, is not guarantee that you do not have COVID-19 infection.

Different possibilities of positive result - look very closely!
Even a faint line at the test region indicates a positive result.

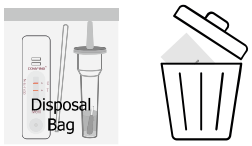




Invalid Result
If the control line "C" is not visible, the result will be Invalid regardless of whether test line "T" is visible.
In case of Invalid result it is advisable to retest with a new cassette and contact the sponsor.

Disposal of Test Kit:

Place the swab, tube and test device into the disposal bag.



Seal the disposal bag and Dispose the bag in a waste bin.

4. Do not use the kit contents beyond the expiry date.
5. Do not touch the nitrocellulose part (Test window and sample well) of the device. Finger print or scratch on nitrocellulose membrane may give erroneous results.
6. Test Devices and Extraction Solutions of different lot must not be mixed and used.
7. Perform the test by using kit's extraction Solutions. Performing the test with any other Solution is not valid.
8. A false negative test may result if the level of antigen in a sample is below the detection limit of the test or if the sample was collected incorrectly.
9. Add sufficient volume of solution into the sample well as suggested for testing.
10. Do not re-use the Test kit components from the procedure; this may lead to aberrant results.
11. Wash your hands thoroughly before and after the test is completed.
12. Avoid contact of reagents with eyes and skin.
13. Do not touch the Swab head as touching will cause the test to be incorrect.
14. Do not store the test kit in direct sunlight.
15. Do not freeze the kit or expose the kit over 30°C.
16. If the amount of solution added into the sample well is excessive or insufficient, an improper test result may occur.
17. The sterilized swab should be used only for nasal specimen collection.
18. Do not eat or smoke while handling specimen.
19. If the swab sticks breaks during specimen collection, dispose the kit and recommence with a new test kit.
20. Bubbles that occur in the extraction tube can lead to inaccurate results. If you are unable to create sufficient drops, this may be caused by clogging in the dispensing nozzle. Shake the tube gently to release the blockage until you observe free drop formation.
21. Cleanup spills thoroughly using an appropriate disinfectant.
22. Place all the items in the disposal bag provided and dispose in a non recyclable waste bin.
23. The test device should remain in its original sealed pouch until usage. Do not use the test device if the seal is broken or the pouch is damaged. In case desiccant pouch changes colour from blue to light pink colour or test device pouch is lack of desiccant then test device should not be used.
24. Once test device foil is opened, it gives accurate result till 24 hours. But, it is recommended that test device should be used immediately.
25. In case of performance changes or product malfunction, stop using the kit immediately and contact customer care.

Influenza B	Staphylococcus epidermidis
Enterovirus	Mycobacterium tuberculosis
Respiratory syncytial virus	Human coronavirus 229E
Rhinovirus	Human coronavirus OC43
Haemophilus influenzae	Human coronavirus NI63
Streptococcus pneumoniae	MERS-coronavirus
Streptococcus pyogenes	SARS-coronavirus
Candida albicans	Parainfluenza 2
Pooled human nasal wash	Parainfluenza 3
Bordetella pertussis	

E. INTERFERING SUBSTANCES:

The following compounds have been tested using the COVID-19 Antigen Test and no interference was observed with Whole Blood, Mucin, Mupirocin, Oxymetazoline, Dexamethasone, Flunisolide, Budesonide Nasal Spray, Phenylephrine, Rebetol, Relenza, Tamiflu,and Tobryaycin.

F. The SARS-CoV-2 variants that can be detected are B.1.1.7 (Alpha), B.1.351 (Beta), P.1 (Gamma), B.1.617.2 (Delta), B.1.427/B.1.429 (Epsilon), Zeta, Eta,P.3 (Theta), B.1.526 (Lota), B.1.617.1 (Kappa), C.37 (Lambda), B.1.617, B.1.617.3 and B.1.618 and omicron

LIMITATIONS:

- The COVIFIND COVID-19 Antigen Self-Test (home use) is designed for the primary the of SARS-CoV-2.
- The results obtained with this test should be interpreted as a presumptive test only and requires confirmation for that follow the guidance from your local state or territory health department for guidance on confirmation testing if necessary and if unwell seek medical assistance.
- A negative or non-reactive test result does not preclude the possibility of exposure to or infection with SARS-CoV-2 virus at any time.
- Failure to follow the test procedure and interpretation of test results may adversely affect the test performance and/or produce invalid results.
- Positive test results do not exclude co-infections with other pathogens.
- The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample storage may affect the test result.
- If the test is not performed within seven (7) days of symptom onset, false negatives may occur.
- A positive result does not guarantee infection.
- The test is less reliable in the later phase of infection and in asymptomatic individuals.

Symbols used on Meril Diagnostics Labels:

REF	Catalogue No.
	Manufacturer
	Manufacturing date
2°C 30°C	Storage temperature
IVD	In Vitro diagnostics
LOT	Batch No.
	Expiry No.
	Keep dry
	Sufficient for
	Caution
	Consult instruction for use
	For single use only do not reuse
	Keep away from direct sunlight
	Do not use if box open or damaged
CE	European health and safety product label
EC REP	Authorized European Representative in European Community
CE 0197	This CE mark concerns sterile nasal swab

Scan the QR code for more information on COVIFIND.

Product Code	Pack Size
CFCAST - 01	01 Test
CFCAST - 02	05 Tests
CFCAST - 03	10 Tests
CFCAST - 04	25 Tests
CFCAST - 05	50 Tests

TGA/CFCAST01/02
Date: 23/12/2022

TEST PROCEDURE:

- The kit should be stored between 2°C to 30°C.
- Wash and dry your hands before commencing test.
- Remove the components from the box and place on a flat surface.
- Remove the Test device from the Pouch.
- Remove the Aluminium Foil from the pre-filled buffer tube.
- Push the buffer tube in to the perforated circle on the front of the box.
- Remove the sterile swab from the tail end. DO NOT touch the swab head.
- Carefully insert the swab into one nostril 2–4 cm or until resistance is met.
- Slowly rotate the swab while rubbing against the sides of the nasal passage at least five (5) times.
- Using the same swab repeat in the other nostril.
- Insert the swab into the buffer tube and swirl it around 8–10 times.
- Pinch the Swab tip through the Tube to remove any remaining fluid.
- Hold the buffer tube firmly and lift the swab till the break point and snap the swab handle.
- Discard the handle for disposal.
- Secure the cap on top of the buffer tube.
- Squeeze four (4) drops from the tube into the sample well of the test device.
- Read the results between 15 and 19 minutes. Beyond 20 minutes and the test is invalid.
- Place the swab, tube and test device into the disposal bag, seal and dispose in a non-recycle waste bin.
- Wash and dry your hands upon completion.

STORAGE AND STABILITY:

- The kit should be stored between 2°C to 30°C.
- In case, the desiccant pouch has changed colour from blue to light pink or colourless, the device should not be used.
- The test device is stable up to the expiration date printed on the outer package.

SPECIMEN STORAGE AND STABILITY:

All Samples should be tested immediately after collection.

PRECAUTIONS:

1. For in-vitro diagnostics use only. Read instructions prior to performing this test, follow all instructions to achieve valid results.
2. Allow all reagents and sample(s) to attain room temperature (18°C to 30°C) before use.
3. Keep the test kit out of reach of children.

USABILITY REPORT:

A usability study was conducted with a pool of 106 lay persons in the self-testing environment. The sensitivity was found to be >90% and the specificity was confirmed to be 100% in the hand of the lay person, comparing with a professional PCR test. Therefore the Summative Evaluation has proven that the usability of the COVIFIND COVID-19 Antigen Self Test ensures a safe and proper use of the device.

PERFORMANCE EVALUATION OF COVIFIND COVID-19 ANTIGEN SELF TEST:

A. Diagnostic Sensitivity:

Overall Diagnostic Sensitivity of COVIFIND COVID-19 Antigen Self Test:

Total 120 SARS-CoV-2 positive nasal swab specimens were tested with COVIFIND COVID-19 Antigen Self Test and 114 out of 120 specimens were detected as positive. So, Diagnostic sensitivity of COVIFIND COVID-19 Antigen Self Test is calculated as 95% (95% CI: 89.43 % to 98.14%). COVIFIND COVID-19 Antigen test kit has 97.10% Diagnostic sensitivity against SARS-CoV-2 Delta and Omicron variant.

B. Diagnostic Specificity:

Overall Diagnostic Specificity of COVIFIND COVID-19 Antigen Self Test:

Total 405 SARS-CoV-2 negative specimens were tested with COVIFIND COVID-19 Antigen Self Test. 405 out of 405 specimens were identified as negative when tested with COVIFIND COVID-19 Antigen Self Test. So, overall Diagnostic specificity of COVIFIND COVID-19 Antigen Self Test is calculated as 100% (95% CI: 99.09% to 100.00%).
COVIFIND COVID-19 Antigen test kit has 100% Diagnostic specificity against SARS-CoV-2 Delta and Omicron variant.

C. Analytical Sensitivity (Limit of Detection):

Limit of detection for COVIFIND COVID-19 Antigen Self Test is 933 TCID 50/ml.

D. Analytical Sensitivity (Cross Reactivity):

The following Cross reactants and microorganisms had no impact on the performance of COVIFIND COVID-19 Antigen Self Test:

Microbial Organisms	
Adenovirus	Mycoplasma pneumoniae
Human Metapneumovirus (hMPV)	Moraxella Catarhallis
Parainfluenza virus - 1	Chlamydia pneumoniae
Parainfluenza virus - 4	Legionella pneumophila
Influenza A	Staphylococcus aureus

- Repeat testing within 1–3 days is recommended in occupational risk, high risk settings or if there is an ongoing suspicion of infection. Reading the results later than 20 minutes will give incorrect results.
- Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
- Possible false test results may occur, if symptoms continue, you should repeat the test after 1-3 days, as the Coronavirus may not be detectable in the very early phase of infection. You are also advised to follow the guidance from your local state or territory health department.

TEST LIMITATIONS:

- The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigen from nasal swab.
- Failure to follow these instructions and interpretation of test results may adversely affect test performance and/or produce invalid results.
- A negative test result may occur if the specimen was collected, extracted or transported improperly.
- If symptoms continue, you should repeat the test after 1–3 days, as the coronavirus may not be detectable in the very early phases of infection.
- Positive test results do not rule out co-infections with other pathogens.
- Reading the test results earlier than 15 minutes or later than 19 minutes may give incorrect results.
- The CoviFind COVID-19 Antigen Self-Test (home use) is not intended to detect from defective (non-infectious) virus during the later stages of viral shedding that might be detected by PCR molecular tests. Therefore, a positive result cannot necessarily determine whether a person is infectious.
- Wait four (4) hours before repeating the test following an invalid result.
- The test is less reliable in the later phase of infection and asymptomatic individuals

REFERENCES:

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- Chan J. F.-W., Kok K.-H., et al. : Genomic characterization of the 2019 novel human-pathogenic coronavirus isolated from a patient with a typical pneumonia after visiting Wuhan.; EMI 2020. doi.org/10.1080/22221751.2020.1719902
- Clinical management of severe acute respiratory infection when Novel coronavirus (nCoV) infection is suspected: interim guidance. WHO(2020): 2020.
- Li, D., Zhang, J. and Li, J., 2020. Primer design for quantitative real-time PCR for the emerging Coronavirus SARS-CoV-2. Theranostics, 10(16), p.7150.
- China National Health Commission, 2020. Diagnosis and treatment of pneumonitis caused by new coronavirus (trial version 6). Beijing: China National Health Commission.

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Diagnostics

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Contact - 02 98461908

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Contact information and online support

Contact the TGA to report poor performance or usability issues in the self test environment (report an issue via the Users Medical Device Incident Report, email iris@tga.gov.au or call 1800 809 361).

State Government COVID Support Line:

State Authority	COVID-19 Helpline	Operational Hours	Website
NSW	1800 020 080	Monday-Friday (8am - 5pm)	https://www.health.nsw.gov.au/
VIC	1800 675 398	Monday-Friday (8.30am-5pm)	https://www.dhhs.vic.gov.au/
QLD	134268	Monday-Friday (8am - 5pm)	https://www.health.qld.gov.au/
NT	1800 490 484	Monday-Friday (8am - 5pm)	https://www.nt.gov.au/
SA	1800 253 787	Monday-Friday (8am - 5pm)	https://www.sahealth.sa.gov.au/
TAS	1800 020 080	Monday-Friday (8am - 5pm)	https://www.tas.gov.au/
WA	1800 595 206	Monday-Friday (8am - 5pm)	https://ww2.health.wa.gov.au/
ACT	1800 022 222	Monday-Friday (8am - 6pm) Weekends & public holidays (8am-5pm)	https://www.health.act.gov.au/